

Atty Docket VASC 1020-2 US

REMARKS

Claims 3, 4, 8, 9, 11, 19-23, 25-26, 38-42, 74-78, 102, 104 and 108 remain in this case.

Claims 3, 4, 8, 9, 23, 25, 26, 38-41, 74-77 and 108 have been rejected as obvious over Herzog '482 in view of Kropf '849. Claim 11 was rejected as obvious over Herzog '482 in view of Kropf '849 and McNamara '370. Claims 19-22, 42 and 78 have been rejected as obvious over Herzog '482 in view of Kropf '849 and Ragheb '904. Claims 101-104 have been rejected as obvious over Herzog '482 in view of Kropf '849 and Hanson '352.

Preliminary Matter

In an Amendment After Final mailed 30 July 2003, claim 38 was amended by changing "and into a hollow body structure of a patient" to "and into a blood vessel of a patient". However, the phrase "and into a blood vessel of a patient" was mistakenly changed to "and into a *what is all of the* blood vessel of a patient" in an unofficial facsimile to the Examiner on 5 September 2003. A second amendment After Final was mailed on 9 November 2003; amended claim 38 carried forward from the facsimile the erroneous phrase "what is all of the". This erroneous phrase has been duplicated in each response since then. Applicant has recently recognized this mistake and has removed the erroneous phrase "what is all of the" from claim 38 in the claim listing above.

The Cited Art

Herzog PCT Publication No. WO 98/08482 discloses coating the surface of, for example, a stent, catheter, etc. with sodium nitroprusside. See page 6. It also discloses a metal stent with grooves along its length. A nitroprusside powder is placed in the grooves in the stent is coated with the PVC solution. The number of coatings, and thus the thickness of the PVC, can be changed to obtain the desired flux of NO. See page 19, example 6.

Hanson U.S. Patent No. 5,399,352 discloses a drug delivery device 10 comprising a first element 4 and a second element 24. The first element comprises an elongate tubular segment 5 comprising a porous clinical vascular graft attached at each end to a severed artery 2. Tubular segment 5 includes a porous portion 28. Porous portion 28 is surrounded by second element 24. A reservoir 20 is formed between porous portion 28 and second element 24. Reservoir 20 can be non-fillable or supplied with an agent through tubing 30. See column 7, line 32-column 8, line 20. This permits the agent to be delivered into the blood flowing through tubular segment 5 so that it can pass with the blood into the interior of the artery.

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Kropf U.S. Patent No. 4,760,849 discloses a planar blank which can be made into a coil spring useful as a filter for thromboses. The coil spring has apertures to facilitate ingrowth of tissue into the spring material. See column 1, lines 61-63 and column 2, lines 51-55. This reference only discloses a stent. It teaches away from adding a graft material because a stated intention of the invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second bioactive layer 22 may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

McNamara U.S. Patent No. 5,147,370 is cited as disclosing a coil with turns touching one another.

The Cited Art Distinguished

It appears that the Examiner is considering the PVC coating of Herzog to be a sleeve as claimed. Applicant disagrees that the PVC coating could be characterized as a sleeve as that term is commonly understood. "1. The part of a garment that covers all or part of the arm. 2. Any encasement or shell into which a piece of equipment fits." *The American Heritage Dictionary of the English Language, New College Edition*, Houghton Mifflin Company, 1976. The PVC coating of Herzog may be characterized as coating or layer, but not a sleeve. However, to clarify the meaning of sleeve in claims 38 and 74, applicant has amended claim 38 to add the substance of claim 101 and has amended claim 74 to add the substance of claim 103.

Claim 38 would not have been obvious over Herzog '482 in view of Kropf '849 and Hanson '352 because there is no suggestions or teaching to modify the disclosed technique of Herzog, in which a PVC solution is used to coat the stent, with a technique which would result in a sleeve defining open regions between the coiled body and the sleeve. Hanson does not teach or suggest this for at least two reasons.

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First, one of ordinary skill in the art would not have combined the proposed combination of Herzog and Kropf as suggested by the Examiner because they are structures used for very different purposes. The Herzog stent is used within a hollow body organ to deliver an agent, nitric oxide, produced by the decomposition of sodium nitroprusside to a target site, such as a blood vessel wall. The Hanson device is typically spliced into a gap in a blood vessel and is used to deliver an agent into the blood flowing through the blood vessel as it passes through the device.

Second, the mere fact that Hanson discloses external reservoir 20 provides no meaningful guidance for modifying the combination of Herzog and Kropf to arrive at the presently claimed invention. That is, Hanson provides no meaningful guidance or instruction as to how one would create open regions between the PVC layer and the stent body of such a combination because Hanson merely teaches the delivery of an agent into the interior of a vascular graft by providing a reservoir of the agent in a region surrounding a perforated portion of the vascular graft.

Accordingly, claim 38 is allowable over the cited art. Method claim 74 is allowable for similar reasons.

The **dependent claims** are directed to specific novel subfeatures of the invention and are allowable that reason is well as by depending from novel parent claims. For example, there is nothing in the cited art suggesting that the prosthesis include a sleeve interior which "is oversized relative to the coiled body so to loosely contain the coiled body" (see **claims 102 and 104**). There is nothing loose about the PVC layer of Herzog.

If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

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